



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------------------|------------------------|
| 10/001,643 | 10/31/2001 | Bradley T. Hyman | 19603/3541 (CRF D-2694A) | 2817 |
| 7590 Michael L. Goldman NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603 | | 01/03/2008 | EXAMINER LAURITZEN, AMANDA L | |
| | | | ART UNIT 3737 | PAPER NUMBER |
| | | | MAIL DATE 01/03/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/001,643 | Applicant(s) HYMAN ET AL. | |
| | Examiner A. Lauritzen | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-14, 18-21, 24-30, 32, 34, 36 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-14, 18-21, 24-30, 32, 34, 36, 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This action is in response to communications filed 4 October 2007. Rejection of claims 10-11 and 25-27 under 35 U.S.C. 101 are withdrawn in view of the amendment to those claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has provided a discussion of each of the references individually, and it is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. The in vivo diagnostic methods of Turner et al. are relevant to the methods claimed regarding disease identification by means of near infra-red radiation. Hochman discloses radiation that is pulsed, and since applicant provides no criticality for the femtosecond pulse range specified, and because this range does not readily appear to provide an advantage over generally pulsing radiation as taught in the reference(s), it is considered to be an obvious matter of design choice within the skill of the art. Hochman further teaches multiphoton excitation in diagnosis of the same diseases claimed [0105], [0124], [0161]. The combination of references and motivation for doing so is clear on the record; therefore the rejection is maintained and repeated herein as appropriate.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed provisional application under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 8-14, 16, 18-21, 24-30, 32, 34, 36 and 38-40 are rejected under 35 U.S.C.

103(a) as being unpatentable over Turner et al. (US 6,329,531) in view of Hochman (US 2003/0236458).

Turner et al. disclose a method for detecting a neurodegenerative disease comprising activating brain tissue by application of radiation under conditions to promote simultaneous photon excitation of the brain tissue and to emit a fluorescence characteristic (refer to the Abstract in which the disease diagnosis is Alzheimer's by applying radiation with wavelength in the visible to NIR region for detection of amyloid plaques in the brain). The photo-active compounds disclosed by Turner et al bind to the A-beta plaques (col. 2, lines 58-64). In-vivo detection of amyloid plaques is characterized as having a laser-induced fluorescence characteristic differing from that in normal tissue and is disclosed to produce an image (col. 2, line 65 – col. 3, line 2; also col. 16, lines 47-52 for applying laser light with wavelength of 740nm). The method of Turner also specifies identification of neurofibrillary tangles (col. 1, line 21).

Turner et al. disclose all features of the invention as substantially claimed as detailed above but are silent with regard to the specifics of the pulsed radiation, carrying out the procedure on a skull that has been thinned or opened, or comparison to a standard fluorescence for making diagnosis. In the same field of endeavor, Hochman discloses diagnosing neurological disorders with an "invasive or semi-invasive" procedure that Examiner understands would include removal of a portion of the skull and/or thinning of the skull to enable access to

the brain (par. 42). Additionally, Hochman describes optical sources providing either continuous or non-continuous (i.e., "pulsed") illumination (par. 41; also par. 146). Hochman discloses comparing patient data to a control and/or standard data set for the purpose of diagnosis and also acquires fluorescence naturally characteristic to the tissue without administering a contrast agent (i.e., "autofluorescence") at par. 45. Hochman further discloses application of energy with a wavelength of about 800nm to analyze deeper areas of tissue (par. 144). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified the method of Turner to include comparison to a standard data set in order to make a diagnosis (as taught by Hochman at par. 45) with removal of impeding bone structure or thinning of the skull as is implied under the invasive brain procedure of Hochman (par. 42) so that pulsed illumination of the area of interest would be possible. It would have been obvious to one of ordinary skill in the art at the time of invention to have provide a pulse width in the femtosecond range with a mode-locked laser in order to concentrate power delivered over a very short time period.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chance (US 5,062,428) for Method and Device for In Vivo Diagnosis Detecting IR Emission by Body Organ, in which a "thin cranium... allows or enhances detection of such [visible light] wavelengths" (col. 4, lines 50-52).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/001,643
Art Unit: 3737

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ALL
12/18/2007

